




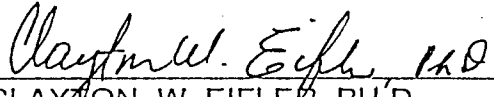
THE ROLE OF AN ORGANIZED EXERCISE AND DIET PROGRAM  
IN THE PRIMARY PREVENTION OF ISCHEMIC CORONARY  
ARTERY DISEASE IN U.S. AIR FORCE AVIATORS

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THE ROLE OF AN ORGANIZED EXERCISE AND DIET PROGRAM IN THE  
PRIMARY PREVENTION OF ISCHEMIC CORONARY ARTERY  
DISEASE IN U.S. AIR FORCE AVIATORS

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Community health protection for asymptomatic ischemic coronary artery disease (ICAD) for U.S. Air Force pilots includes a regulation (AFI 48-123), which requires screening of cholesterol levels. If an officer is not qualified on initial exam, he does not begin pilot training. If a qualified pilot develops a disqualifying condition, the test is repeated in about 3-6 months after "prudent diet" modification. If he confirms disqualifying cholesterol levels, he is then grounded and may have to receive a mega-workup to rule out ICAD, including a coronary artery angiogram evaluation at Brooks AFB, TX. To avoid this mega-workup, many flight surgeons are prescribing medications such as lovastatin to improve cholesterol levels, without giving a diet and exercise program a legitimate trial to work.

The Air Force has developed a health promotions program which has been generally underutilized. Current practice is that almost no pilots, identified

with medically disqualifying cholesterol levels, are referred to the health promotions program. This practice has been witnessed by the author as a practicing flight surgeon at 3 Air Force Bases, and has been verified by interview with more than 12 flight surgeons at more than 12 different Air Force Bases in the United States and overseas. Since military pilots are trained at U.S. taxpayer expense and the training costs usually exceed \$1 million to be fully combat capable, and since these pilots are responsible for multimillion dollar aircraft, it makes economic sense that these pilots be held to high standards of professional and physical fitness in order to defend our country.

Therefore, given the governance of the military on pilots, policy changes can be made which pilots should be willing to incorporate into their lives, if these policy changes contribute positively to their overall health and maintenance of flight status. Results of several clinical trials demonstrate that diet and/or exercise programs improve cholesterol levels. These trials strongly suggest that an organized program of exercise and diet can make a significant clinical difference by lowering both total cholesterol and the TC/HDL ratio in USAF aviators at risk, thereby decreasing the incidence of ischemic coronary artery disease.

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## **Introduction**

An organized exercise and diet program should be considered the first step as primary therapy for Air Force Aviators who should lower their plasma cholesterol levels, and thus decrease their risk for ischemic coronary artery disease (ICAD).

## **Background and Review of the Literature**

Results from the famous Framingham Heart Study of hypertensive patients indicate that high density lipoprotein (HDL) plasma levels and the total cholesterol to HDL ratio (TC/HDL) are the most powerful factors for predicting ICAD.<sup>7</sup> High HDL is inversely related with ICAD incidence, while high TC/HDL ratios and high levels of low density lipoprotein (LDL) are both positively correlated with ICAD (and statistically significant).<sup>22,31</sup> Another famous cohort study performed on Harvard alumni demonstrated that exercise was independent of other influences on heart attack rate, and that men who maintained <2000 kcal expended per week in exercise were at 64% higher risk for heart attack than men who maintained >2000 kcal expended per week in exercise.<sup>4</sup>

Heart disease is the leading cause of morbidity and mortality in the United States today and more money is spent on its treatment than any other

condition -- over 50 billion dollars per year in the 1990's.<sup>12,23</sup> Although mortality rate due to heart disease has declined since 1970, the hospitalization rate due to heart disease has increased over 25% from 1970 to 1986.<sup>9</sup> The CDC reported in 1989, that the population attributable risk of cholesterol levels >240 mg/dl was 33.2% for coronary heart disease mortality in 1986.<sup>8</sup> According to G. E. Alan Dever, health care professionals in Georgia estimate that about 54% of contribution to heart disease is due to personal lifestyle.<sup>14</sup> The Framingham cohort heart study showed that over an 8 year period 24.2/1000 males who were initially asymptomatic developed symptomatic ICAD in the 30-39 y.o. age group. The numbers were 66.3/1000 for 40-49 y.o. and 131.3/1000 for 50-59 y.o.<sup>7</sup>

For the Air Force, recently published data shows that an average of 7.6 active aviators suffer cardiac events each year in a population averaging about 30,000.<sup>48</sup> Approximately 250 catheterizations are performed on asymptomatic aviators at risk for ICAD at Brooks Air Force Base aeromedical consult service each year, and a recent retrospective study showed that among the aviators with angiographically demonstrated disease, 88% had a TC/HDL ratio >6.0. The ratio was >6.0 in only 4% of aviators who had no disease at catheterization.<sup>64</sup>

Since hypercholesterolemia and low HDL levels are the most significant risk factors for heart disease, we should institute the best therapy available to

correct these problems with individual patients. Modification of diet (along with weight loss) and drug therapy have become mainstays of the medical profession in treating hypercholesterolemia. The Centers for Disease Control and Prevention (CDC) recently reported that the prevalence of overweight adults (>20% over ideal body weight) in 1994 was ~34.9%, compared with 33.3% in 1988 and 25.4% in 1980.<sup>10</sup> This upward trend in obesity has been attributed to Americans leading a more sedentary lifestyle (i.e. lack of exercise, partially caused by the television, automobile, and computer society), even though we appear to talk a lot about healthy living.<sup>12</sup> However, exercise has not been widely recognized as an important form of primary prevention. Current leading articles on treatment of hypercholesterolemia only briefly mention exercise, and put main emphasis on diet and drug therapy.<sup>12,21,32,38</sup> Current theory is that high cholesterol causes atherosclerosis of the coronary arteries which blocks normal blood flow, but that this process can be stopped, or even reversed, if serum cholesterol levels are modified to appropriate levels.<sup>47,61</sup>

Community health protection for asymptomatic ischemic coronary artery disease for U. S. Air Force Pilots includes a regulation (AFI 48-123), which requires screening of cholesterol levels (i.e. total cholesterol (TC), HDL, LDL, and VLDL) during a "long" physical exam every 3 years, along with the initial Flying Class I exam before a person begins undergraduate pilot training. The

disqualifying results include a TC over 230 if the TC/HDL ratio is over 6.0 or LDL over 160, or a TC over 300 (irregardless of the other values).<sup>1</sup>

If an officer is not qualified on initial exam, he does not begin pilot training. If a qualified pilot develops a disqualifying condition, the test is repeated in about 3-6 months after "prudent diet" modification. If he confirms disqualifying cholesterol levels, he is then grounded and may have to receive a mega-workup to rule out ICAD, including a coronary angiogram evaluation at Brooks AFB, Texas. To avoid this mega-workup, many flight surgeons are prescribing medications such as lovastatin or gemfibrozil to improve cholesterol levels, without giving an exercise and diet program a legitimate trial to work. In a clinical trial of 232 patients who were prescribed a prudent diet by their personal physicians, Singh demonstrated that when these patients were not monitored, their follow-up labs in 12 weeks showed no significant change in cholesterol values.<sup>58</sup> Air Force aviators are treated similarly, leading to many being treated medically. If the medication brings cholesterol levels within the defined values, a flight waiver is requested and the pilot is kept on the medication permanently.<sup>2</sup>

The Air Force has developed a health promotions program which has been generally underutilized. Current practice is that almost no pilots, identified with medically disqualifying cholesterol levels, are referred to the health promotions program. This practice has been witnessed by the author

as a practicing flight surgeon at 3 Air Force Bases, and has been verified by interview with more than 12 flight surgeons at more than 12 different Air Force Bases in the United States and overseas.

### **Purpose**

The purpose of this study is to determine if an organized exercise and diet program can make a significant difference in lowering both total cholesterol and the TC/HDL ratio in USAF aviators at risk for ischemic coronary artery disease, and if this improvement would be enough to avoid drug treatment intervention as discussed above. Background review of the medical literature has revealed several articles which link hypercholesterolemia and sedentary lifestyle epidemiologically to ischemic coronary artery disease.<sup>7,49</sup> Several medical journal articles have also been written which report the results of clinical trials demonstrating how diet and/or exercise programs can improve cholesterol levels.

### **Methods and Procedures**

Given the results of the qualitative review of the literature described above, several clinical intervention trials were evaluated to determine the effectiveness of an organized exercise and/or diet program in significantly improving the TC/HDL ratio to reduce the risk of ischemic coronary artery

disease. The results from 15 published clinical intervention trials were compiled in a Microsoft Excel spreadsheet in order to analyze the trends of the studies. The rationale for using the Excel spreadsheet was for ease of comparison of several trials and for accurate calculations concerning the data reported in each trial.

The criteria for including an intervention trial in the Excel spreadsheet for trend analysis included the following: 1) publication in a medical journal (verifying peer review), 2) data published concerning total cholesterol and HDL cholesterol values for patients (and controls, if used) both before and after treatment intervention, 3) treatment intervention used only exercise and/or diet changes (e.g. no medications used), and 4) sample size given so that p values could be verified/calculated, in order to determine statistical significance. A few good clinical intervention trials which were not able to be included in the Excel spreadsheet were also evaluated and are discussed in the Results section.

## **Results**

The results of the Excel spreadsheet analysis of 15 studies meeting the above listed criteria are displayed in Figure 1, with pertinent conclusions for each study displayed in Figure 2.

FIGURE 1: EXERCISE AND DIET STUDIES - COMPARISON OF CHOLESTEROL LEVELS														
STUDY	TC		HDL		TC/HDL		HDL		TC/HDL		HDL		TC/HDL	
NO. #	PRE	POST	DIFF	PRE	POST	DIFF	PRE	POST	DIFF	PRE	POST	DIFF	PRE	POST
DIET ONLY														
1	21	229	181	-48	41	34.5	-6.5	5.59	5.25	-0.34	NS	TCL SIGNIF LOWERED		
2	3	171	136	-35	40	34	-6	4.28	4.00	-0.28	NS	TCL SIGNIF LOWERED		
3	11	254	208	-46	46	39	-7	5.52	5.33	-0.19	NS	TCL SIGNIF LOWERED		
EXERCISE ONLY														
3	6	209	194	-15	50.6	58.6	8	4.13	3.31	-0.82	<.05	WEIGHT TRAINING		
4	9	218	210	-8	38	53	15	5.74	3.96	-1.77	<.01	AEROBIC EXERCISE		
5	20	236	215	-21	46	48	2	5.13	4.48	-0.65	<.001	AEROBIC EXERCISE		
7	25	127.4	134.2	6.8	41.5	54.7	13.2	3.07	2.45	-0.62	<.001	MILITARY RECRUITS		
EXERCISE AND DIET														
8	79	232.2	185.8	-46	54.2	46.4	-7.8	4.28	4.00	-0.28	<.01	DIET & EXERCISE (D&E)		
9	4587	231.6	175.2	-56	39.8	35.2	-4.6	5.82	4.98	-0.84	<.01	RESIDENCE PGM, D+E		
EXERCISE AND DIET WITH CONTROLS														
10	11	170.6	149.3	-21	35.3	43.4	8.1	4.83	3.44	-1.39	<.05	OBESSE CHILDREN, D+E		
CONTR	14	176.9	167.1	-9.8	29.5	32	2.5	6.00	5.22	-0.77	NS			
11	89	248.2	212.6	-36	45.1	49.6	4.5	5.50	4.29	-1.22	<.02	INDIA MIDDLE CLASS, D+E		
CONTR	232	243	235.4	-7.6	45.3	43	-2.3	5.36	5.47	0.11	NS			
OTHER STUDIES WITH CONTROLS														
12	14	173	164	-9	35	45	10	4.94	3.64	-1.30	<.01	WEIGHT TRAINING		
CONTR	14	175	180	5	40	36	-4	4.38	5.00	0.63	NS			
13	15	202.6	202.4	-0.2	47.3	56.1	8.8	4.28	3.61	-0.68	<.01	AEROBIC EXER/ ELDERLY		
CONTR	15	202.9	192.7	-10	45.5	42.1	-3.4	4.46	4.58	0.12	NS			
14	31	207	199	-8	43	49	6	4.81	4.06	-0.75	<.05	MILD AEROBIC EXERCISE		
CONTR	29	223	244	21	46	50	4	4.85	4.88	0.03	NS			
15	13	201	192	-9	46	53	7	4.37	3.62	-0.75	<.01	WEIGHT TRAINING		
CONTR	8	188	185	-3	49	47	-2	3.84	3.94	0.10	NS			



## FIGURE 2

### RESULTS

#### Study 1:

26 days of high-complex carbohydrate, low fat, low cholesterol, high fiber diet.

#### Study 2:

Diet of calories distributed with 40% carbohydrate, 40% fat, and 20% protein. The polyunsaturated/saturated (p/s) ratio was changed from 0.4 for two weeks to 2.0 for two weeks.

#### Study 3:

4 weeks each of comparing a high saturated fat diet with a high monounsaturated fat diet.

#### Study 4:

16 weeks of progressive weight training for 45-50 min per session at 3 times per week.

#### Study 5:

7 years of jogging and cycling for 50-60 min per session at 4-6 times per week.

#### Study 6:

30 weeks of aerobic exercise for 1 hour each day, beginning at 3 days/week and progressing to 6 days/week.

#### Study 7:

12 weeks of intense physical activity averaging 11,603 kcal/wk for 6 weeks, then 24,625 kcal/week for 6 weeks (25 Israeli military recruits 18-20 y.o.).

#### Study 8:

3 weeks of mild aerobic exercise (walking) for 45-90 min. per session at 5-7 days per week. Diet provided <10% calories from fat, >35 g of fiber, and high-complex carbohydrates (79 people ave age of 58 y.o., with ~52% males).

### CONCLUSIONS

This diet significantly lowered plasma cholesterol levels, without significantly changing the TC/HDL ratio.<sup>55</sup>

Increasing the P/S ratio will decrease all cholesterol levels, so that the TC/HDL ratio remains the same.<sup>29</sup>

Changing from a saturated fat to a monounsaturated fat diet will result in lower cholesterol levels, but it does not improve the TC/HDL ratio.<sup>26</sup>

Continuous weight training improves TC/HDL ratio.<sup>24</sup>

Continuous aerobic exercise improves TC/HDL ratio, which continues to improve even after 1 year of exercise.<sup>54</sup>

Continuous aerobic exercise improves TC/HDL ratio.<sup>17</sup>

Both aerobic and weight resistance continuous physical conditioning improve the TC/HDL ratio, although to a lesser extent if the ratio is already low.<sup>56</sup>

When diet is combined with exercise, total cholesterol is reduced and TC/HDL ratio is reduced, thereby giving an additive effect.<sup>5</sup>

## FIGURE 2 (continued)

### Study 9:

3 week in-residence life-style modification program, including daily aerobic exercise and a high fiber, low fat (<10%) diet.

Monitored program yields good results. Total chol and the TC/HDL ratio were both significantly improved with diet + exercise.<sup>3</sup>

### Study 10:

20 weeks of aerobic exercise for 50 min per session at 3 times per week. Also, a nutritionist guided a balanced diet to achieve 1-2 lbs weight loss per week.

When exercise is combined with diet, the cholesterol levels are improved more favorably than they are by diet alone.<sup>6</sup>

### Study 11:

12 weeks of aerobic exercise for >5 days per week and a diet monitored by a nutritionist. The control group ate a prudent diet advised by their physicians. Diet + exercise diaries were kept.

A monitored exercise & diet program can result in a significant improvement in the TC/HDL ratio.<sup>58</sup>

### Study 12:

9 weeks of resistance exercise using free weights and machine gym equipment, for 60-80 min sessions 3 times per week.

Moderate resistance exercise significantly improves TC/HDL levels.<sup>20</sup>

### Study 13:

9 months of aerobic treadmill exercise under guidance of an exercise physiologist, achieving ~50% max VO<sub>2</sub>. Elderly 50:50 male to female ratio >65 years old.

Continuous aerobic exercise significantly improves the TC/HDL ratio. Additionally, 1 month of detraining in 5 patients showed a significant increase in the TC/HDL ratio.<sup>44</sup>

### Study 14:

8 weeks of walking and jogging for 9-15 miles per week.

Mild regular aerobic exercise significantly improves the plasma TC/HDL ratio.<sup>52</sup>

### Study 15:

12 weeks of weight training upper and lower body for 45-60 min sessions at 3 times per week. Diet monitored, with no significant change in either group.

Regular resistance weight training significantly improves plasma TC/HDL ratio.<sup>30</sup>

### Overall Conclusions:

Comparing these studies demonstrates the epidemiological principles of strength of association and consistency in all studies. Notice how studies 8 and 9 demonstrate that a low fat diet will decrease the HDL along with the TC, but with exercise the TC will be lowered in greater proportion, and therefore the TC/HDL ratio will still be significantly improved. In addition, a dose - response relationship can be seen in that study 8 demonstrated a small (but significant) change with walking (mild aerobic exercise), whereas studies 4, 10, and 5 demonstrated increasingly larger improvements as exercise intensity and time passage increased.

Comparing these studies demonstrates the epidemiological principles of strength of association (with significant p values for the intervention group) and consistency in all studies. Notice how studies 8 and 9 demonstrate that a low fat diet will decrease the HDL along with the TC, but with exercise the TC will be lowered in greater proportion, and therefore the TC/HDL ratio will still be significantly improved. In addition, a dose - response relationship can be seen in that study 8 demonstrated a small (but significant) change with walking (mild aerobic exercise), whereas studies 4, 10, and 5 demonstrated increasingly larger improvements as exercise intensity and time passage increased. An additional important conclusion to point out from this review is that diet treatment alone will decrease both TC and HDL, thereby yielding no significant change in TC/HDL ratio. Since a low HDL level has been shown to be an independent risk factor for ICAD,<sup>7,23,27</sup> then this trend analysis shows strong argument that both exercise and diet should to be used together in a treatment program to lower risk for ICAD.

Additional studies which demonstrate a favorable relationship between exercise and TC/HDL ratios which were not amenable to the Excel spreadsheet include those by Herbert and Quig.<sup>28,51</sup> Herbert conducted a prevalence study comparing 5 runners to 5 inactive men, which showed that although the runners had an average TC of 39 mg/dl more than the inactive men, their average TC/HDL ratio was lower by 0.8. Quig showed that the

opposite results of the 15 trials on the Excel spreadsheet could be demonstrated. That is, he had a study group of 12 men consume a high cholesterol diet (1400 mg/day) and be sedentary for 4 weeks. There was a significant increase in both TC and the TC/HDL ratio for the group.

Superko reported several studies in 1994 demonstrating reversal of plaque formation in coronary arteries after increasing HDL and reducing LDL through both nonpharmacologic and pharmacologic treatment (verified by coronary arteriography).<sup>61</sup> Ornish also demonstrated regression of coronary atherosclerotic lesions by angiography after cholesterol lowering intervention of lifestyle changes, including exercise, diet and stress management (no drug intervention).<sup>47</sup> A major newspaper recently reported that Dr. Ornish has been conducting a study funded by Mutual of Omaha insurance company since 1993. By using these lifestyle changes alone, the average annual medical costs for his 507 heart disease patients were \$3,826, versus \$13,927 for similar heart disease patients who were not participating in his program.<sup>19</sup>

## **Discussion**

Comparisons between trials can suffer from a series of methodological shortcomings due to differences in sample size, protocols, quality of study conduct and other factors (e.g. incomplete reporting).<sup>50</sup> However, given these limitations, and the wide variation of results found in the intervention studies

discussed above, we still find a trend of strength of association between an organized exercise and diet program, and reduction of serum TC/HDL ratios. There was consistency between studies, and a dose - response relationship corresponding to the amount of change in exercise and diet.

Epidemiologically, we have seen through several prospective cohort studies, perhaps most notably those reported by Castelli and Paffenbarger,<sup>7,49</sup> how a high TC/HDL ratio and lack of an exercise maintenance program both are significantly associated with increased risk/incidence of ICAD.

Conversely, the Lipids Research Coronary Primary Prevention Trial reported that for every 1% reduction in cholesterol, one should expect a ~2% reduction in risk for ICAD.<sup>39,40</sup>

Two autopsy studies on casualties of the Korean and Vietnamese wars reported how there was gross evidence of coronary atherosclerosis in >45% of the men whose average age was ~22 years old for both studies.<sup>16,43</sup> There was no known clinical ICAD, and for the Vietnam study of 105 autopsies, only one heart demonstrated any degree of stenosis by angiography. These studies help define the nature of ICAD, which begins with asymptomatic atherosclerosis while young, gradually builds up stenosis over time, and eventually can obstruct coronary arteries. Biological plausibility is therefore demonstrated by a high TC/HDL ratio and sedentary lifestyle hastening the deposition of cholesterol plaques, leading to early symptomatic ICAD.

## Conclusions and Recommendations

As mentioned in the Results section above, both exercise and diet should be used together in an organized treatment program to optimize reduction of risk for ICAD. Given the various clinical intervention trial results, we can estimate that an aggressive exercise and diet program can achieve an average reduction of 0.75 to 1.5 in the TC/HDL ratio, which should greatly reduce the need for drug intervention to allow aviators to stay within Air Force medical requirements on cholesterol levels. A significant advantage over drug treatment is that this program would also reduce the ICAD independent risk factor of inactivity, which has a population attributable risk (PAR) percent similar to a TC of >240.<sup>8</sup> Other additional benefits of an organized exercise and diet program which are not realized with drug treatment include decreased obesity, decreased resting blood pressure, decreased cancer risk, and decreased risk for diabetes mellitus.<sup>36,59</sup>

Given the Air Force average rate of 7.6 adverse ICAD events per year and the potential to reduce risk of ICAD by ~25% with an organized exercise and diet program,<sup>40,45,65</sup> this program could potentially reduce the ICAD average incidence rate by 1.9 aviators per year and save the Air Force (and the American taxpayer) ~\$2 million per year (average cost to train a combat qualified pilot exceeds \$1 million<sup>4</sup>). In a recent Air Force Times article,<sup>42</sup> the surgeon general was quoted as stating that lifetime healthcare for career

military personnel is no longer affordable. As in the civilian world, the cost of treating heart disease outweighs the cost of treating any other condition in the Air Force medical system. Since an organized exercise and diet program would only require redirection of resources already in place (e.g. flight medicine clinics, health + wellness centers, and monitoring with reports to higher headquarters), there would be a small (but noticeable) implementation cost and a smaller yearly maintenance cost; but these costs will be far exceeded by future savings from decreased hospital/medical treatment of symptomatic ICAD (including angina, angioplasty, acute myocardial infarction, and coronary artery bypass surgery). The savings from no longer necessary cholesterol-reducing drugs alone (~\$300 per patient per year), would probably more than adequately pay for administration of this primary prevention exercise and diet program.

As mentioned in the Results section, Dr. Dean Ornish has conducted a study funded by Mutual of Omaha insurance company since 1993, and using lifestyle changes alone, the annual medical costs for his 507 heart disease patients were \$3,826 versus \$13,927 for similar heart disease patients who were not participating in his program - a savings of over \$10,000 per year for each patient.<sup>19</sup> Of course, this is secondary prevention, but given the above information on how to identify people at high risk for developing ICAD, there is much potential for saving both morbidity and medical costs through primary

prevention treatment with an organized exercise and healthy diet program for these high risk people.

A policy should be developed to standardize an exercise and diet program for use by all USAF flight surgeons involved in treating pilots with hypercholesterolemia. This program would involve use of the health promotions program and records would be maintained. AFI 48-123 should require results of at least 6 months in the exercise and diet program be documented in the pilot's medical record before considering medical treatment. This improvement on a universal Air Force scale should help reduce the current incidence of 7.6 cardiac events per year for aviators alone, and therefore save millions of dollars in training replacement pilots and in medical costs. Overall quality of life would also improve for the pilots in the program.

A pilot study should be performed to test the effectiveness of an exercise and diet program and to learn the most efficient way to implement the program Air Force wide. Given the potential savings in future healthcare costs discussed above, an efficiently run program which targets the people at highest risk for developing symptomatic ICAD will benefit the entire Air Force population, including nonflying personnel. A pilot study project to test the organized exercise and diet program is discussed on the following pages.



## **Exercise and Diet Program Pilot Study Project**

Study strategy: We will use a clinical trial, identifying aviators at risk for ICAD and randomizing them into a control group of current Air Force practice or into a treatment group of an organized exercise and diet program, with patient education and routine weekly follow-up of progress with an exercise physiologist and nutritionist. Standardized protocols will be completed before the study begins (please see Appendix A for general protocols regarding exercise and diet). After 3 and 6 months, treatment versus control groups will be compared for statistically significant improvements in TC and TC/HDL ratios.

### **Specific Design of the Pilot Study Project:**

Population at risk - Air Force aviators who have a serum total cholesterol level of  $>230$  and/or a TC/HDL ratio  $>5.5$ .

Recruitment of participants in the study - The Flight Wings at 8 Air Force bases would be asked to participate, as we expect an average of 20 aviators in each Wing to meet the "at risk" criteria. Flight physical exams for the past 3 years on all Wing aviators will be screened. If any cholesterol values are missing or aviators are borderline at risk, they will be called in for

lab analysis. All patients identified at risk will be educated on the study objectives and informed consent will be obtained.

Variables - The independent variables will be treatment versus control group. The dependent variables will be total cholesterol, HDL, and TC/HDL ratios recorded at start of study, at 3 months, and at 6 months into the study. To control for possible confounders, age will be stratified by 21-29 y.o., 30-39 y.o., 40-49 y.o., and 50-59 y.o. for randomization purposes. All laboratories will use a standardized machine and protocol for obtaining values. All AFB's will use the same treatment protocols and be routinely inspected for compliance. Any medications which alter serum lipid values will be discontinued and "washed out" of the patient's system before beginning the 6 month study. After informed consent is obtained, patients will be randomized into a treatment or control group, stratified by age. If any females are identified, they will be randomized equally or be analyzed separately.

Ethics - Confidentiality will be maintained and appropriate medical follow-up, after the study is completed, will be performed at each base's flight medicine clinic.

Statistical Considerations for the Pilot Study Project: Sample size required for this study is determined to be 114, using Epi Info software (see appendix A).<sup>18</sup> Power = .9, and alpha error probability = .05. To be

conservative, we want to detect an improved TC/HDL ratio (defined as the "disease" for Epi Info purposes of calculation) with a risk ratio of 2.5 for treatment versus control group (e.g. if the control group improves the TC/HDL ratio by .2, then the treatment group would need to improve the TC/HDL ratio by .5 to be statistically significant). Also, to allow for up to 20% drop-out rate, we want to recruit 142 patients for our study.

Data will be collected by each base flight medicine clinic and transmitted to the NCOIC of this study at Brooks AFB, Texas (please see Appendix B for the project organization chart). Each base flight surgeon will verify the validity of data before it is transmitted. The project director will analyze the data using the pooled 2 sample T-test. Results can then be displayed by a table comparing before and after study results for the treatment group versus control group.

Administration for the Pilot Study Project: As mentioned above, a general standardized protocol for the exercise and diet part of the program is listed in Appendix A. The pilot study project organization structure is shown in Appendix B. Appendix C shows the planned project schedule, with the scope of work itemized on the left side. Required project resources, a project budget request with justification, and a project control plan are listed in Appendices D, E, and F respectively.

Expected Results of the Pilot Study Project: The results should be statistically significant, given the results of prior clinical intervention studies discussed above. In addition, this study should demonstrate by how much the TC/HDL ratio and TC can be reduced by an organized Air Force exercise and diet program utilizing or redirecting resources already available (i.e. flight medicine clinics and health + wellness centers). For example, if a pilot can reduce his TC/HDL ratio by 1.0 -1.5 (e.g. from 6.0 to 4.5), then he not only remains medically qualified for flight duty (without the use of medication which requires a waiver), but he also significantly reduces his risk for symptomatic heart disease.

Discussion of Strengths: Since this is a prospective and controlled study, there should be a minimum of bias and confounding. There have been several similar studies involving diet or exercise in the past, but few good studies which involve combined exercise and diet as treatment to change the risk factors of cholesterol levels in a favorable direction. A secondary result in some of our study participants should be a decrease in the risk factor of obesity.

Discussion of Weaknesses: Although the aviators will be randomized to treatment or control group, there is possible confounding of treatment patients who do not want to put forth maximum effort for behavior change in exercise

and diet. Conversely, there may be control patients who do not want to miss out on the individualized treatment program and may seek exercise and diet counseling like their colleague(s) are receiving. We would request the control patients make no changes to their lifestyles until after the 6 month trial period.

Conclusion and Recommendation for the Pilot Study Project: This project's goal is to establish the effectiveness of, and to emphasize, that an organized exercise and diet program should be the first step in treating hypercholesterolemia in Air Force pilots. The results of the exercise and diet program study project should be used to develop the Air Force policy change recommended in the above thesis conclusion.

## APPENDIX A

### Exercise Protocol:

1. Aerobic exercise (including running, treadmill, stationary bicycle, versaclimber, stairmaster, or equivalent) to achieve 70 - 75% maximum heart rate for at least 40 minutes, 3 times weekly.
2. Weight training for 45 - 60 minutes at least 2 times weekly with a minimum of 3 sets each for 8 exercises, including all body parts (e.g. arms, shoulders, back, chest, abdomen, legs).
3. An exercise diary will be kept and checked weekly during a follow-up visit with the exercise physiologist.

### Diet Protocol:

1. Maximum daily calories tailored to each individual to achieve optimal body weight for height and frame - to be determined with standard charts by a nutritionist. Weight loss goal not to exceed 2 lbs/week.
2. A diet diary will be kept by the patient and checked weekly during a follow-up visit with the nutritionist.
3. Goal would be to have a diet with calories composed of 60 - 70% mostly high-complex carbohydrates; 10 - 20% protein derived from mostly chicken, fish, or vegetable source; and less than 20% fat which has a >2:1 ratio of polyunsaturated to saturated fats. Fiber intake at 40 grams/day and cholesterol intake at less than 300 mg/day.

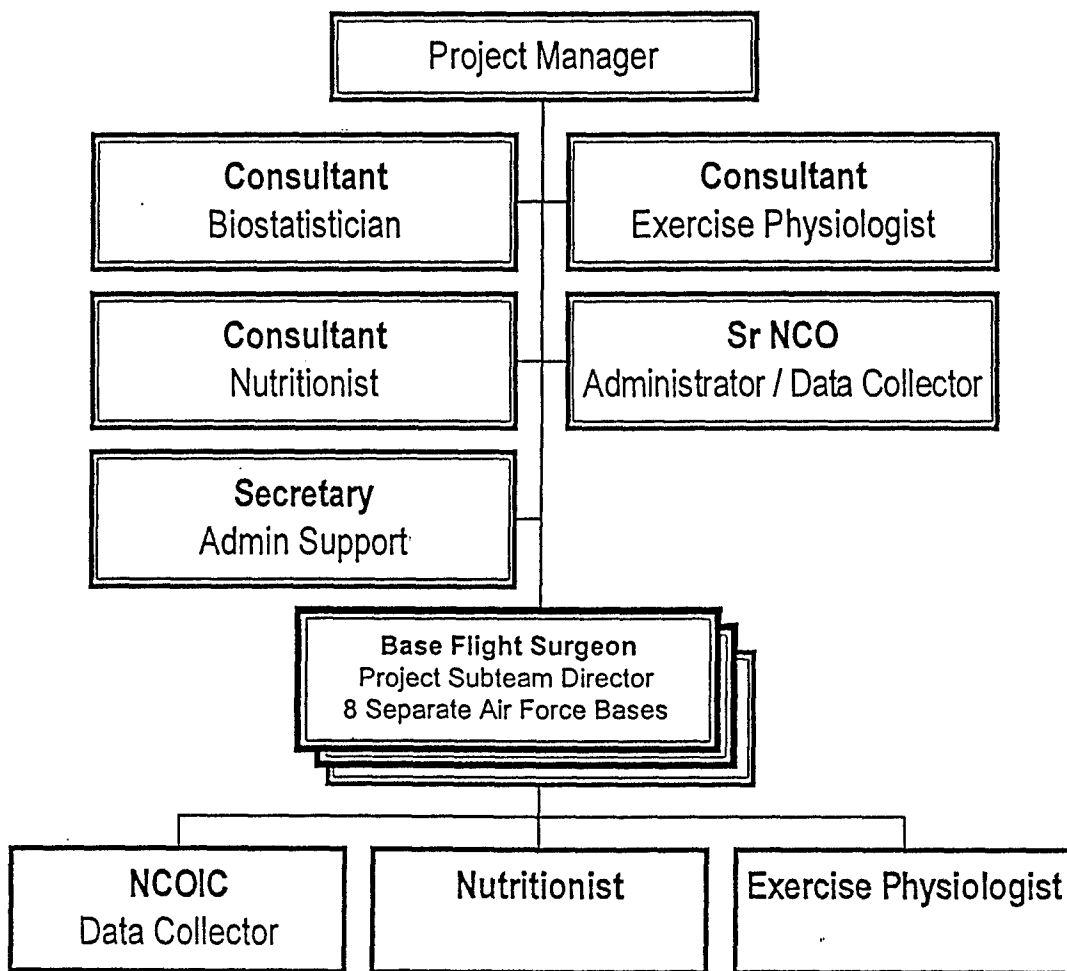
### Epi Info Computer Printout:<sup>18</sup>

Conf.	Power	Unex:Exp	Disease in Exposed	Risk Ratio	Odds Ratio	Sample Size		Total
						Unexp.	Exposed	
95.00 %	90.00 %	1:1	50.00 %	2.50	4.00	57	57	114
90.00 %	"	"				48	48	96
95.00 %	"	"				57	57	114
99.00 %	"	"				79	79	158
99.90 %	"	"				109	109	218
95.00 %	80.00 %	"				45	45	90
"	90.00 %	"				57	57	114
"	95.00 %	"				69	69	138
"	99.00 %	"				94	94	188
"	90.00 %	4:1				136	34	170
"	"	3:1				111	37	148
"	"	2:1				84	42	126
"	"	1:2				44	87	131
"	"	1:3				38	115	153
"	"	1:4				36	143	179

Formula :  $m' = \frac{\text{Sq}\{c(a/2)*\text{Sqrt}[(r+1)*PQ]-c(1-b)*\text{Sqrt}[r*P1Q1+P2Q2]\}}{(r*\text{Sq}[P2-P1])}$   
 $m = .25m'*\text{Sq}[1+\text{Sqrt}[1+2*(r+1)/(m'*r*\text{Abs}[P2-P1])]]$

APPENDIX B

## Exercise & Diet Project Organization Chart



# APPENDIX C: PROJECT SCHEDULE, INCLUDING SCOPE OF WORK

ID	Task Name	Duration	Qtr 2, 1997			Qtr 3, 1997			Qtr 4, 1997			Qtr 1, 1998			Qtr 2, 1998		
			Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1	Plan Project	3w															
2	Permission, Funding and Resources	3w															
3	Write Protocols	5w															
4	Organize and Train Project Team	3w															
5	Educate Subteams	3w															
6	ID Aviators at Risk (Est. Base Labs)	14w															
7	Educate Aviators (Informed Consent)	15w															
8	Randomize	14w															
9	6 Mo. Rx Program	40w															
10	Feedback Requests	35w															
11	Retest Labs	139d															
12	Retest 3 Month Labs	14w															
13	Retest 6 Month Labs	13w															
14	Statistical Analysis	79d															
15	Statistical Analysis (3 Mo. Labs)	3w															
16	Statistical Analysis (6 Mo. Labs)	3w															
17	Feedback to/from Subteams/Aviators	3w															
18	Report to Authorizing Officials	2w															
19	Project Closedown	3d															



## APPENDIX D

### Resource Summary

### Exercise and Diet Project

#### Resource:

#### Total time or amount of equipment:

#### A. Personnel:

- |                                      |                   |
|--------------------------------------|-------------------|
| 1. Project Manager                   | 1. 69 days        |
| 2. Biostatistician-consultant        | 2. 7.5 days       |
| 3. Secretary                         | 3. 6.5 days       |
| 4. Sr NCO / Admin & data collector   | 4. 32.5 days      |
| 5. Exercise Physiologist-consultant  | 5. 23.5 days      |
| 6. Nutritionist-consultant           | 6. 23.5 days      |
| Subteams - 8 each at different AFB's |                   |
| 7. Flight Surgeon                    | 7. 13 days x 8    |
| 8. Flight Med NCOIC data collector   | 8. 13.5 days x 8  |
| 9. Exercise Physiologist             | 9. 11.5 days x 8  |
| 10. Nutritionist                     | 10. 11.5 days x 8 |

#### B. Space:

- |  |  |
|--|--|
| 1. Office work   | 1. The usual for each person listed above                                  |
| 2. Patient interview and counseling at clinics           | 2. Appointments arranged for project participants as they are for patients |
| 3. Base gym for exercise program (including instruction) | 3. Available at each base  |

#### C. Equipment:

- |   |  |
|---|--|
| 1. PC with e-mail capability at each base | 1. 9 PC's--already in place                  |
| 2. Copy machine with paper                | 2. Central staff--already in place           |
| 3. Computer software                      | 3. Windows 95, Microsoft Office, and Minitab |
| 4. Office supplies                        | 4. For central staff and 8 AFB's x 1 year    |

#### D. Transportation:

- |  |   |
|--|---|
| 1. Educate/train subteams for Project Manager, Admin Sr NCO, Exercise Physiologist, and Nutritionist | 1. 16 day road trip from Brooks AFB to the 8 AFB's selected by the commander.     |
| 2. Site visits to above AFB's by Project Manager for quality control and 1-minute managing           | 2. At least 2 TDY visits to each base listed above between weeks 10-48 of project |
| 3. Project results presentation at an international symposium  | 3. Project Manager and Project Subteam Directors                                  |

#### E. Communication:

- |  |  |
|--|--|
| 1. Telephone with autovon, local, and long distance access | 1. 9 each - already in place for project duration at all 8 sites |
| 2. FAX machines  | 2. 9 each - as above   |
| 3. E-mail  | 3. See PC above  |

#### F. Supplies for computers and offices

1 yr supply x 9 sites

## APPENDIX E

### Budget Request and Justification by Key Objective

Legend: P=personnel, E=equipment, Sp=space, Su=supplies, T=transportation, C=communications, PM=project manager, B=biostatistician, S=secretary, NCO=admin Sr NCO, EP=exercise physiologist, N=nutritionist, FSX=flight surgeon, EPX=base exercise physiologist, NX=base nutritionist, NCOX=base NCO

<u>Key Objective</u>	<u>Resources required &amp; amount of time</u>	<u>Justification</u>
1. Developing project plan and research design	<p>P - project manager--2 weeks @ 1/2 time</p> <p>P - biostatistician--3 days @ 1/2 time</p> <p>P - secretary--2 days</p> <p>E - PC w/ MS Office &amp; Minitab software</p> <p>Sp - offices usually used by personnel above</p> <p>Su - computer and office supplies</p> <p>C - autovon, long distance, &amp; local telephone access</p>	<p>To develop a doable project which will give us statistical significance of <math>H_0</math> vs <math>H_A</math>. Typed in an efficient and understandable format.</p>
2. Obtain permission, funding, and resources	<p>P - PM (included above)</p> <p>P - NCO--4 days</p> <p>P - S (included above)                      E - PC</p> <p>Sp - offices usually used by personnel above</p> <p>Su - computer &amp; office supplies</p> <p>C - Autovon local access, FAX</p>	<p>Paperwork must be completed and submitted to obtain permission and funding. The NCO will obtain all resources necessary.</p>
3. Educate and train staff	<p>P - PM--4 days total</p> <p>P - B--2 days      P - N--2 days      P - EP--2 days</p> <p>E - power point projector      Sp - small classroom</p> <p>S - project participant equipment packets</p>	<p>The central key staff must be trained on project goals and objectives. Job descriptions and standards will be discussed with each staff member.</p>
4. Write standardized protocols for treatment, including daily Rx diary, lab testing, exercise, diet, and behavior change rationale	<p>P - PM--3 days</p> <p>P - EP--2 days</p> <p>P - NCO--2 days</p> <p>E - PC                      Sp - offices as above</p> <p>Su - as above                      C - as above</p>	<p>Each consultant will have major input in the protocols, which will be typed by the secretary. The NCO will ensure standardization of all lab procedures between bases (including same type equipment).</p>

# APPENDIX E (continued)

5. Educate and train subteams	<p>P - PM--19 days TDY</p> <p>P - EP--19 days TDY</p> <p>Subteam (8 each):</p> <p>    P - FSX--2 days</p> <p>    P - NX--2 days</p> <p>E - power point projector at each base</p> <p>Sp - small classroom at each base</p> <p>C - as above</p> <p>T - for central key staff to each AFB</p> <p>Su - project participant equipment packets</p>	<p>P - N--19 days TDY</p> <p>P - NCO--19 days TDY</p> <p>P - EPX--2 days</p> <p>P - NCOX--2 days</p>	<p>Each subteam staff will be educated and trained on the project goals and objectives, along with their job description and standards at their own base. These site visits also allow inspection for appropriate resources at each base.</p>
6. Identify aviators at risk	<p>P - FSX--2 days x 8</p> <p>P - NCOX--5 days x 8</p> <p>P - PM--1 day to review and adjust</p> <p>E - PC, as above</p> <p>Sp - Flight Medicine Clinic and Laboratory</p> <p>Su &amp; C - as above, also lab slips</p>		<p>Medical records on aviators assigned to the base must be reviewed for cholesterol levels on most recent flight physical. Any values over 3 years old or any unknown values will require that the aviator to be called in for testing.</p>
7. Randomize aviators to treatment and control groups	<p>P - B--1/2 day</p> <p>P - NCO--1 day</p> <p>E - PC</p> <p>Sp - office</p> <p>Su &amp; C - as above</p>		<p>Biostatistician with aid from the NCO to communicate with each base and start computer data base.</p>
8. Educate aviators at risk and obtain informed consent	<p>P - FSX--1 day</p> <p>P - EPX--2 days</p> <p>P - NX--2 days</p> <p>Sp - clinics</p> <p>E - as above</p> <p>Su &amp; C - as above</p>	<p>(1/2 hr appt w/ FSX and 1 hr appts with EPX &amp; NX for treatment. Estimate 10 - 12 aviators per base)</p>	<p>Each treatment aviator must be educated on behavior change to lower his cholesterol levels. Authority and rationale should come from his flight surgeon.</p>
9. 6 month treatment trial with feedback	<p>P - FSX-- 8 days total</p> <p>P - NX--3 hrs/wk x 26 weeks</p> <p>T - For PM TDY site visits</p> <p>E - as above, and exercise equipment at gym</p> <p>Su &amp; C - as above</p>	<p>P - EPX--3 hrs/wk x 26 weeks</p> <p>P - PM--28 days total</p> <p>SP - clinics and gym</p>	<p>Treatment as outlined in protocols. Follow-up appts at various intervals with FSX to evaluate progress. PM to evaluate quality control and standards met.</p>

# APPENDIX E (continued)

10. Retest labs at 3 and 6 months	P - FSX--1/2 day total P - NCOX--1 day total SP - as above, & laboratory E, Su, & C - as above	NCOX arranges for aviators to have cholesterol tests, retrieves results, gives to FSX for evaluation.
11. Collection of data from subteams	P - NCO--3 days total P - NCOX--1 day total at each AFB E, Sp, Su, & C - as above	Data must be accurately retrieved and recorded at each base, and then accurately transmitted to (and stored by) the central staff for analysis.
12. Statistical analysis of data	P - PM--1 day P - B--1 day E, Sp, Su, & C - as above	Biostatistician and project manager analyze results of intervention trial IAW previously set protocol.
13. Feedback to/from subteams	P - PM--2 days P - EP,N,NCO,FSX,EPX,NX,NCOX--1/2 day each (includes the 8 subteams) E, Sp, Su, & C - teleconference center--1/2 day for each base	Document valuable lessons learned from the project by all key staff to enhance future projects by us or others with similar goals & objectives.
14. Report to authorizing officials	P - PM--1 day P - B--1/2 day P - S--1/2 day E, Sp, Su, & C - as above	Formatted report IAW previously set quality standards -- for submission to authorities on results of project.
15. Project closedown	P - PM--3 days P - NCO--3 days P - S--2 days E, Sp, Su, & C - as above	Ensure all information gathered from project is organized for future retrieval and that all resources used are redirected appropriately. Prepare for journal publication.

## APPENDIX F

### Exercise and Diet Project Control Plan

#### 1. Resource Acquisition:

Personnel resources (including salaries and benefits) all work for the Air Force and will have agreed upon the work time involved if the project is approved by the commander. The equipment, space, supplies, and communication are all listed in the Budget Request and will be available by the end of week 2 (Books, diaries, and pens will be distributed when subteams are trained). The Admin Sr NCO will ensure resources are in place by the end of week 2, and give a report to Project Manager.

#### 2. Costs and Expenditures:

The above listed resources are funded by the Air Force and the AETC fiscal officer will calculate total cost in quarterly intervals based on our budget request submitted and the staff's actual time sheets submitted monthly to resource management. The column code on everybody's sheet for the project is LOVAS. Cumulative expenditures comparing actual to projected will be provided to the Project Manager by the AETC fiscal officer every month, beginning with 2 weeks of information (2 weeks lag time preparation). Each Air Force Base Health and Wellness Center will provide "The Living Heart Food Shopper's Guide" book by Michael E. DeBakey, pens, exercise & diet diaries, and exercise charts for project participants with a one month lead-time request. Brooks AFB Armstrong Lab will provide for travel and per diem costs of project staff from the annual research budget. Each travel itinerary will be scrutinized by the Admin Sr NCO, with a monthly report given to the Project Manager to assure least cost used (e.g. commercial vs space A military travel and on-base billeting). The incentive to keep travel costs down is that the remainder of the travel budget (after the project is completed) may be used to fund as many staff as possible to present the project results at an international medical symposium.

#### 3. Key Objective Performance:

Controlled through the Project Schedule Chart (Appendix C) with milestone objectives at the end of each task. Meeting Quality Standards will be evaluated by the Project Manager weekly and especially when a milestone is reached. Deviations from the schedule should be predicted as early as possible and any changes must be discussed with and approved by the Project Manager.

#### 4. Project Effectiveness:

Preliminary effectiveness can be evaluated at the 24-28 week point with lab data and feedback. If results are not encouraging, or are disparate between locations, the treatment procedures need to be inspected to ensure protocols are being followed appropriately. Also feedback may encourage changes which will be evaluated for incorporation into the project without biasing the data analysis and being able to maintain project goals. Effectiveness will be continuously evaluated during at least 2 site visits to each project base by the Project Manager between weeks 8 and 48. Of course, at the end of the project, complete biostatistical analysis will be done to accomplish the goal of evaluating the effectiveness of this exercise and diet treatment program.

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## VITA

Philip J. Lavalley [REDACTED], the son of Richard H. Lavalley and Priscilla J. Lavalley. After graduating from Inter-Lakes High School in Meredith, New Hampshire, he enlisted in the Army in 1976, serving in the Airborne Infantry. In 1980, he received a Bachelor of Science degree in Animal Science from Iowa State University and was commissioned as an officer in the Regular Army. After serving tours in Alaska, Germany, and various posts in the southeastern United States, he matriculated to Dartmouth Medical School in New Hampshire in 1987. He received his Doctor of Medicine degree in 1991, and has practiced with the Air Force since that time. In 1996, he began the three year Residency in Aerospace Medicine by matriculating to the University of Texas School of Public Health (San Antonio). In 1982, he married Michelle J. Nowack and they have 5 children - Eva, Priscilla, Philip Jr., Georgianna, and Morgan who were born in [REDACTED] respectively.

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This thesis was typed by the author and his wife.

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